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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/046,504	10/19/2001	Steven J. Siegel	PENN-0789	3358

7590 10/19/2006
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EXAMINER

FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
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1618

DATE MAILED: 10/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/046,504	Applicant(s) SIEGEL ET AL.	
	Examiner Blessing M. Fubara	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 August 2006.
 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4 and 6-10 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) ☐ Claim(s) _____ is/are allowed.
 6) ☒ Claim(s) 1,3,4 and 6-10 is/are rejected.
 7) ☐ Claim(s) _____ is/are objected to.
 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Examiner acknowledges receipt amendment and remarks filed 2/16/06. Claims 1 and 4 are amended. Claims 2 and 5 are canceled. Claims 1, 3, 4 and 6-10 are pending.

Claim 1 is amended to recite specific biodegradable polyesters.

Response to Arguments

Any previous rejections that are not reiterated herein, have been withdrawn.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 3, 4 and 6-10 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Mao et al. (US 6,166,173).

Mao discloses biodegradable medical implant devices that incorporates from about 1% to about 65% active agent (abstract, column 21, lines 8-11; column 22, lines 34-44), the active agent includes antipsychotic drugs (column 20, lines 1 and 2); the biodegradable polymers are polyesters (column 2, lines 27-33; column 12, lines 52, 53, 61, 62; column 13, lines 3, 4, 15). While there is long list of drugs, if the desire is to incorporate antipsychotic drugs, then the antipsychotic drug is clozapine, haloperidol or risperidone (column 20, lines 1 and 2) can be

Art Unit: 1618

used. The biodegradable implant is prepared by melt process (column 22, lines 34-40) or by compression molding at 50 °C (column 24, lines 47-58). Regarding claim 9, the antipsychotic drug may have effect over schizophrenia. Mao discloses that a single entity or combination of entities may be used and thus, regarding claim 10, a combination of antipsychotic drugs may be used with the expectation of producing synergistic effect.

The antipsychotic drug is used in amounts of 1-65% in Mao while haloperidol (antipsychotic drug) is in amount of 20-40% in the claims. The recited amount of the haloperidol in the claims lies within the disclosed range in Mao. Furthermore, Mao discloses that polylactide, polyglycolide and poly(lactide-co-glycolide) are used as biomedical implants (column 2, lines 27-29). Since claim 1 is directed to a composition/system that consists essentially of biodegradable polymer selected from the group consisting of polylactide and lactide-co-glycolide copolymer and since in claim 2, the polymer can be polylactide when the %amount of the glycolide is "0", it stands to reason that Mao would meet the limitations of the polymer requirement of claims 1 and 2 when polylactide is used as the polymer. The difference, therefore, between Mao and the instant claims is the amount of the haloperidol where the disclosed amount encompasses the claimed amount. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the biodegradable implant of Mao by compression molding of discs or melt process and incorporate the amount of active agent such as haloperidol or clozapine or risperidone antipsychotic drugs in amounts of from 1-65% that would be effective to produce the desired antipsychotic effect.

Response to Arguments

3. Applicant's arguments filed 8/03/06 have been fully considered but they are not persuasive.

Applicant argues that

- a) Mao discloses a string list of potential drugs without providing data to show the stability and/or release and/or undesirable side effects such as tissue necrosis for any of the exemplary antipsychotic drugs. Applicant states that it is not all pharmaceutical agents or antipsychotic agents that were found to be amenable to the delivery system of the instant claimed invention.
- b) That the Y-L-Y sequence in Mao is different from the random polylactide and lactide-co-glycolide copolymers of the instant claims; and that Mao uses biodegradable polymers that contain phosphorus.

Response:

Regarding a), it is noted that when considering antipsychotic drugs, the list is quite limited to clozapine, haloperidol or risperidone and any of them including haloperidol can be incorporated in the implant. Secondly regarding lines 14-27 of page 2 of the specification, it is noted that the specification specifically mentions "thiothixene" as having decreases stability ... when drug concentrations are increased. While applicant refers to this passage, it is further noted that clozapine, haloperidol or risperidone was not mentioned as ones whose stability decreases with increasing concentration. Also, applicant provided no factual evidence that haloperidol of Mao would not be amenable to the invention, rather it is noted that the paragraph

Art Unit: 1618

cited by applicant states that haloperidol has been demonstrated to be suitable in applicant's invention.

Regarding b), it is noted that Mao does suggest the use of polylactide, polyglycolide and poly(lactide-co-glycolide) polymers in implants. The claims do not recite random copolymers.

No claim is allowed.

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1618

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Blessing Fubara
Patent Examiner
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SUPERVISORY PATENT EXAMINER